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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,028	06/25/2001	Niva Shapira	01/22156	8373

7590 06/17/2004

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EXAMINER	
WEINSTEIN, STEVEN L	
ART UNIT	**PAPER NUMBER**
1761	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

A8

Office Action Summary	Application No.	Applicant(s)	
	09/887,028	SHAPIRA, NIVA	
	Examiner	Art Unit	
	Steven L. Weinstein	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *8-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolridge et al (Lancel-1980) in view of Stehlin (FDA Consumer 6/96), Kavanagh (Food Ingred.11/95), Uhle (Milchwissen Schaft, 1974) and Zubkova et al (Int'l Dairy Congress, or vice versa, ie Stehlin, Kavanagh, Uhle and Zubkova et al in view of Woolridge et al.

It is noted that the examiner has been unable to obtain a full text copy of Woolridge et al, so the reference is being construed to relate to modified human milk, as opposed to "formula".

In regard to claim 1, Woolridge et al discloses feeding infants human milk that has been modified to provide a lower fat milk and a higher fat milk which milk is designed to simulate the change in milk composition during breast feeding. The two modified milks (low and high fat) are placed in separate bottles and then fed to infants one after the other (i.e sequentially) during the same feeding. Claim 1 differs from Woolridge et al in that instead of using lower and higher fat modified human milk, a lower and higher fat infant formula is employed. As noted previously, Stehlin, Kavanagh, Uhle and Zubkova are relied on to teach that it was well established in the art to provide infant formulas which simulate, copy, reproduce, or imitate human breast milk. Since Woolridge et al already teaches that the fat content during breast feeding changes and also teaches simulating the change in fat content that occurs during breast feeding by feeding a lower fat content milk and then a higher fat content milk, to modify Woolridge et al and substitute two formulas having a lower and higher fat content for the two

modified milk portions would therefore have been obvious. It would appear to be irrelevant what the ultimate objective of Woolridge et al is, since Woolridge et al, whatever the objective, unequivocally teaches that fore and hind milk natural breast feeding can be simulated outside the breast by supplying beverages having two different fat concentrations and feeding the infant through a dispensing container. Similarly, employing Stehlin, etc. as the primary reference, since Stehlin, Kavanagh, Uhle, and Zubkova disclose it was notoriously old to replicate, as close as possible, human breast milk, and since it was known that human breast varies in fat content during a feeding (Woolridge et al) and since it was known to replicate such fat content change by feeding the infant two beverages having different fat contents (Woolridge et al), (first low, then higher fat content), to modify Stehlin and the art taken as a whole and prepare two formulas that replicate the fore (low fat) and hind (high fat) and feed the infant these formulas sequentially at the same feeding session would therefore have been obvious. It is also noted that the ultimate objective of Woolridge et al is to determine if changes in composition of human milk affect milk intake. But the changes in composition Woolridge et al speak of, is the change in fat content. Thus, the emphasis really is on the change of fat content of the milk that occurs in human milk. This does not teach away from the prior arts attempt to replicate milk as much as possible.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Simmons et al ('776) who is applied for the reasons given in the Office action mailed 10/27/03.

All of applicants remarks filed 2/25/04 have been fully and carefully considered but are not found to be convincing. Since the 35 USC 102 rejection has been withdrawn in view of the amendment, the remarks concerning this rejection are moot. Note, however, in regard to claim 3,

wherein it is urged that Woolridge et al does not teach gradual admixing, claim 3 is an alternative claim, i.e. it recites one after the other or gradually admixed, so that Woolridge et al would not have to show gradual admixing for the rejection to be proper. In regard to the rejections under 35 USC 103, the urgings address Woolridge et al, but do not address the rejection over the art taken as a whole as set forth in the last Office action.

The remainder of the references cited on the USPTO 892 form are cited as further art of interest.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Steven Weinstein at telephone number (571) 272-1410.

Weinstein/tgd

June 1, 2004

STEVE WEINSTEIN
PRIMARY EXAMINER (761)
6/15/04